

**Meeting of the
Pharmacy and Therapeutics Committee
April 22, 2008**

Members Present:

Randy Axelrod, M.D., Chair

Mark Oley, R.Ph., Vice Chair

Gill Abernathy, M.S., R.Ph.

Avtar Dhillon, M.D.

James Reinhard, M.D.

Rachel M. Selby-Penczak, M.D.

Renita Driver, Pharm.D.

Tim Jennings, Pharm.D.

Roy Beveridge, M.D.

Reuben Varghese, M.D.

Absent:

Mariann Johnson, M.D.

Arthur Garson, M.D.

A quorum was present

Guests:

79 representatives from pharmaceutical companies, providers, advocates, associations, etc.

DMAS Staff:

Patrick Finnerty, Agency Director

Cheryl Roberts, Deputy Director of Programs and Operations

Bryan Tomlinson, Director, Division of Health Care Services

Usha Koduru, Counsel to the Board, Office of the Attorney General

Rachel Cain, Pharm.D., Clinical Pharmacist

Keith Hayashi, R.Ph., Clinical Pharmacist

Katina Goodwyn, Pharmacy Contract Manager

Maryanne Paccione, Information Management Consultant

Meredith Lee, Policy Analyst

First Health Staff:

Debbie Moody, R.Ph, Clinical Manager, Virginia

Doug Brown, R.Ph, M.B.A., Dir. of Rebate Contracting Management

Sandy Kapur, Pharm.D, Rebate Support

Donna Johnson, R.Ph, Clinical Manager, Virginia

KATINA GOODWYN'S DEPARTURE

Dr. Axelrod announced that Katina Goodwyn would be leaving DMAS. He expressed the Committee's thanks for all of her support and organizational help over the past few years. He said that Katina has helped him, Patrick Finnerty, Cheryl Roberts, the Committee, and everyone at DMAS. He said that Katina has been the Pharmacy Administrator for quite some time. She has helped keep everything on track and in order. He said that on behalf of the Committee, he wanted to thank her for her dedication and the tremendous service she gave to the P&T Committee. Dr. Axelrod and Patrick Finnerty presented Katina with a plaque. Dr. Axelrod concluded by saying that the Committee appreciates everything Katina has done for them and that she would be missed.

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Patrick Finnerty started by thanking Katina for her organization and management of the P&T Committee. He thanked her for the tremendous job. He confirmed that the Committee would miss her in the future, but that they are happy for her as she moves on in her career.

Patrick Finnerty welcomed the Committee to the meeting. He noted that seven of the Committee members have been on the Committee since its inception. He thanked the Committee members for their contribution to the Committee and commented that the PDL continues to be very successful and that the success of the PDL is due, in part, to the Committee's efforts. Mr. Finnerty thanked the new member, Dr. Varghese, for his attendance.

Mr. Finnerty reviewed the new Tamper-Resistant Prescription Pad requirements that were put into place on April 1, 2008. The law was enacted by Congress and applies to most prescriptions for Medicaid patients in the fee-for-service program. If it's a written prescription it has to be written on a tamper-resistant prescription drug pad. DMAS has worked with the Pharmacy Association, a lot of physician groups, the Medical Society of Virginia, and others to make this transition as easy as possible. So far, there haven't been any serious problems. Mr. Finnerty noted that this is another mandated program and DMAS is trying to make this an easy transition.

Mr. Finnerty reminded the group that on May 23, 2008, the requirement to use the National Provider Identification Number (NPI) would go into effect on all claims submissions from all health care providers, including pharmacy-related claims. NPI is a national requirement.

Mr. Finnerty informed the group that a provision in the Deficit Reduction Act (DRA) that affects all physician-administered drugs in an outpatient hospital setting goes into effect on July 1, 2008. To comply with this federal law, DMAS will require hospital providers who provide physician-administered drugs in outpatient hospital settings to include National Drug Code (NDC) information on the drug dispensed on all electronic and paper claim submissions. He noted that DMAS is working with Virginia hospitals and the Virginia Hospital and Healthcare Association. Mr. Finnerty explained that this requirement was originally scheduled to go into effect on January 1, 2008, but DMAS received an extension until July 1, 2008 (although DMAS asked for a much longer extension) and hopes to extend the date until January 1, 2009, because DMAS wants to give the hospitals the time they need to accomplish the necessary system changes.

Mr. Finnerty closed by thanking the Committee and the audience for their work and efforts towards the PDL. He commented that they are great resources for the PDL program.

COMMENTS AND WELCOME FROM DR. RANDY AXELROD, CHAIRMAN

Dr. Axelrod welcomed Dr. Reuben Varghese to the Committee. He recognized that Dr. Varghese is currently the Medical Director of the Arlington Health District within the Virginia Department of Health. He has more than 15 years of experience as a practicing physician and is board certified in Preventative Medicine. Dr. Varghese's prior positions include serving as a Medical Epidemiologist and a Medical Officer for Surveillance and Medical Affairs. Dr. Axelrod explained that Dr. Varghese would replace Dr. Katherine Nichols who left the Virginia Department of Health and returned to private practice. Dr. Axelrod acknowledged the Committee's appreciation for Dr. Nichols' time and commitment during her time.

Dr. Axelrod reviewed the agenda noting that the Committee would review two potential new drug classes for PDL eligibility, new drugs in phase I PDL, and the annual phase II PDL review. In addition, Dr. Axelrod mentioned that the final guidance document to clarify the generic drug policy as it relates to PDL drug classes would be reviewed.

Dr. Axelrod reminded the Committee that at the last meeting the Committee reviewed and approved two new drug classes on the PDL (Hepatitis C and Growth Hormones). As an update to the Committee, Dr. Axelrod noted that there have been no issues to date with the implementation of these new classes on the PDL. The First Health Clinical Call Center reports the following for the first three months (January 1st to March 31st):

- **Growth Hormones** – Total of 51 authorization requests for the clinical edit (required for all scripts), 8 total requests for non-preferred drug(s), and a total of 116 claims for these medications.
- **Hepatitis C** – Total of 29 authorization requests for the clinical edit and 104 claims for these medications.

Dr. Axelrod reminded the Committee that some clinical materials included in the notebook are confidential and copy written. He said that the documents should not be copied in any other fashion.

Dr. Axelrod noted that there were 19 speakers and he reviewed the guidelines for the presentations.

ACCEPTANCE OF MINUTES FROM OCTOBER 3, 2007, MEETING

Dr. Axelrod asked if there were any corrections, additions, or deletions to the minutes from the October 3, 2007, meeting minutes. With no comments, the minutes were accepted as written.

REVIEW OF DRAFT GUIDANCE DOCUMENT FOR THE GENERIC DRUG POLICY (SEE FINAL GUIDANCE DOCUMENT ATTACHED)

Dr. Axelrod reminded the Committee that at last meeting they reviewed a draft of the guidance document to clarify the generic drug policy as it relates to drug classes subject to the PDL. He referred them to the notebooks to inspect the latest revisions, which include:

- Consistent use of the term “therapeutically equivalent” throughout the document;
- Clarification on the ultimate decision making authority by the Department (with recommendations from First Health Services and in consultation with the P&T Committee Chair or other designated member); and
- Integration with the existing “PDL Generic Drug Policy”.

Dr. Axelrod reminded the Committee that the goal of the guidance document to clarify the generic drug policy is to achieve the more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes. In addition, it will allow best pricing to be maintained during the exclusivity period until it is financially conducive to change to the generic.

Dr. Axelrod asked for comments from the Committee. There were no recommended changes, additions or clarifications. A motion was made to accept the guidance document to clarify the generic drug policy as written. The motion was seconded and unanimously approved by the Committee.

Drug Class Reviews

To allow practicing physicians to return to their practices, Dr. Axelrod called speakers and reviewed classes in a different order than noted on the agenda.

Phase II PDL Annual Review: Central Nervous System Stimulants/ADHD Medications

Sandra Baucom, MD, Pediatrician, Renaissance Pediatrics, discussed Daytrana (methylphenidate transdermal patch). Dr. Baucom is a speaker for Shire Pharmaceuticals.

Dr. Axelrod asked if there is any diversion with the patch.

Dr. Baucom replied that there is none because once the patch is removed it cannot be reapplied.

Tim Jennings confirmed that he was not aware of any diversion issues.

Edward John Kuhnley, MD, Child & Adolescent Psychiatrist, Central Virginia Community Services Board, Child & Family Division (Lynchburg), discussed Vyvanse™ (Lisdexamfetamine Dimesylate LDX). Dr. Kuhnley noted that he is a speaker for Shire Pharmaceuticals.

No questions or comments from the Committee.

Shonda Foster, PharmD, MS, MPH, Neuroscience Outcomes Liaison, Eli Lilly and Company, discussed Atomoxetine/ Strattera

No questions or comments from the Committee.

MARK OLEY REVIEWED CNS: ANTIHYPERKINESIS/STIMULANTS (MEDICATIONS FOR ADD/ADHD)

Liquadd® (Dextroamphetamine sulfate), an amphetamine, is now approved in an oral solution (5 mg/5 ml), for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This product will be

launched during the second quarter of 2008. *Post meeting clarification: This is a new dosage formulation from Auriga Laboratories, Inc.*

Mark Oley motioned that the Antihyperkinesia/CNS Stimulants continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider Antihyperkinesia/CNS Stimulants to be PDL eligible.

Phase II PDL Annual Review: Antibiotics/Anti-infective

Dr. Brent Armstrong, Internal Medicine Physician, discussed Factive (Gemifloxacin) (Third Generation Quinolones - Systemic). Dr. Armstrong noted that he was a speaker for Oscient Pharmaceuticals.

Dr. Axelrod asked if Factive comes in blister packs of five, seven, or does it come separate.

Dr. Armstrong said that it comes in five and seven-blister packets.

Dr. Axelrod asked what the AWP price was and if the 5-tablet pack was 40% less expensive than the 7-tablet pack.

An answer was not available for Dr. Axelrod during the meeting.

Amy McKay, Scientific Affairs Liaison, Ortho-McNeil Janssen Scientific Affairs, LLC, discussed Levaquin (Third Generation Quinolones)

No questions or comments from the Committee.

TIM JENNINGS REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: 2ND & 3RD GENERATION QUINOLONES

There are many Quinolones on the market. Cipro is the first quinolone to go generic. The difference between Cipro and Gemifloxacin, Levofloxacin, and Avelox is that Cipro works on Pseudomonas and the others are active for Streptococcus pneumoniae, Haemophilus influenzae, Mycoplasma Pneumoniae, and Chlamydia Pneumoniae for Community-Acquired Pneumonia. The concern with these agents is overuse and increased resistance. Levofloxacin has been highly utilized. It is now available for high-dose, short-course therapies in both an intravenous and oral 750 mg dosage formulation to be administered once daily for five days. *Post meeting clarification: It is now approved for the treatment of complicated Urinary Tract Infections and Acute Pyelonephritis.*

The adverse drug profile needs to be considered in these drugs. In the beginning, they were all equal, but, now, to some extent, Gemifloxacin, Levofloxacin, and Avelox have all been found to cause QTc prolongation to some degree. They need to be monitored or avoided all together in Cardiac patients.

Factive (Gemifloxacin) manufactured by Oscient has a new dosage regimen of 320 mg orally once daily for five days for treatment. Gemifloxacin given longer than 7 days usually causes a rash to develop, so therapies are short courses to reduce the incidence of rash.

Tim Jennings motioned that the Second and Third Generation Quinolones continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider the Second and Third Generation Quinolones as PDL eligible.

New Drug in PDL Phase 1- Sanctura XR- Urinary Tract Antispasmodics

Richard Graham, MD, Urological Specialists of Virginia, discussed Sanctura XR (Urinary Tract Antispasmodics). Dr. Graham is a speaker for all of the Antispasmodics manufacturers.

Dr. Axelrod asked how someone would pick one drug over the other if all the drugs are equally efficacious. Dr. Graham said that one would pick based on the side effect profile. He said that CNS side effects can be significant, so you pick the safest.

MARK OLEY REVIEWED URINARY TRACT ANTISPASMODICS AND DISCUSSED SANCTURA XR®

Sanctura XR is now available in an XR formulation (Trospium Chloride, extended release). The FDA approved the new dosage form made by Indevus Pharmaceuticals, Inc. It is a muscarinic receptor antagonists now approved in a once-daily formulation for treatment of overactive bladder.

Mark Oley motioned that Sanctura XR be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Sanctura XR as PDL eligible.

Review of Potential New Drug Class-DPP-IV Inhibitors

Christine Arsever, MD, Senior Medical Director, Merck & Co., Inc., discussed Januvia (DPP-IV Inhibitors)

Gill Abernathy asked in what patients Januvia™ alone would be recommended.

Dr. Arsever said in patients who are unable to tolerate Metformin; it can be used as an initial monotherapy.

Dr. Axelrod asked how often Januvia™ was being used as first-line therapy.

Dr. Arsever said that she did not have that information, but that she did not think it was very often. Tim Jennings said he believed it was around 15% of the time.

TIM JENNINGS REVIEWED HYPOGLYCEMICS, DPP-IV INHIBITORS

Januvia™ has been on the market about a year and no adverse events have been seen. This is a benefit of the drug. The dipeptidyl peptidase-4 (DPP-4) inhibitors are indicated for treatment of diabetes. Januvia™ is approved for use as monotherapy, or in combination with Metformin or a thiazolidinedione. Januvia™ is used as an initial therapy, in combination with Metformin, or as an add-on therapy with a sulfonylurea or as add-on therapy with both a sulfonylurea and Metformin. These are used as therapeutic options after diet and exercise, Metformin or TZDs have failed. Sitagliptin provides a lowering of HbA_{1c}, (baseline HbA_{1c} < 10 percent – it will obtain a HbA_{1c} reduction of –0.6 percent). Januvia™ and Janumet™ are currently available in this class. Both are made by Merck and the generic names are Sitagliptin and Sitagliptin/Metformin, respectively. Tim Jennings noted that the precautions include lactic acidosis due to Metformin, so use should be avoided in patients with liver disease.

Tim Jennings said that according to the 2006 American Diabetes Association guidelines, TZDs, insulin, and sulfonylureas are second-line options, following an inadequate response to Metformin. Janumet may compete with other agents, such as Actoplus Met and Avandamet as second-line to initial Metformin therapy in type 2 diabetics. No comparative studies with other antidiabetic products are currently available. Most studies have been as additive therapy with Metformin. No long-term outcome studies have been completed yet.

Tim Jennings motioned that the DPP-IV Inhibitors be PDL eligible. The motion was seconded. The Committee voted unanimously to consider DPP-IV Inhibitors as PDL eligible.

Dr. Axelrod noted that, in the future, this class would have a new mechanism of action within the Oral Hypoglycemics.

Review of Potential New Class-Topical Antibiotics

Melissa A. Szymczak, PharmD, Medical Information Scientist, GlaxoSmithKline, discussed Altanax (Topical Antibiotics)

Dr. Axelrod asked why GlaxoSmithKline makes 10 and 15 gram tubes if a 5 gm course was indicated.

Dr. Szymczak said that you should not need more than 5 grams for 100 square centimeters.

MARK OLEY REVIEWED TOPICAL ANTIBIOTICS

Mark Oley noted that Impetigo could be treated with oral antibiotics as well as topical antibiotics. He relayed to the Committee that there are three basic products included in this class: Mupirocin Ointment (generic); Bactroban Cream (Mupirocin); and Altabax™ (Retapamulin Ointment).

Mark Oley motioned that Topical Antibiotics be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Topical Antibiotics as PDL eligible.

New Drug in PDL Phase 1- Bystolic-Beta-Blockers

Michael McGuire, PharmD, BCPS, Cardiovascular Therapeutic Specialist, Forest Research Institute, discussed Bystolic (Beta-Blockers)

Gill Abernathy asked where this drug was going with respect to congestive heart failure studies.

Dr. McGuire replied that Nebivolol (Bystolic™) is indicated in Europe for heart failure and they plan to meet with the FDA to seek that indication in the United States.

Dr. Axelrod asked if NICE in the UK had reversed their recommendations on beta blockers.

Dr. McGuire replied that yes they have. Recent meta-analysis suggest that beta blockers may not have a centrally blood pressure lowering effect in part because of their mechanism of action. They are looking at Bystolic™ to see how it compares.

Tim Jennings asked what advantage this product has over other similar agents. He also asked what makes this a new agent.

Dr. McGuire replied Bystolic™ is different because it vasodilates through nitric oxide release. The difference between this and a traditional beta blocker is that it has a more balanced hemodynamacis; it is very beta 1 selective and does not have as many side effects as other beta blockers.

Mark Oley asked if Bystolic™ has less contraindications than other beta blockers.

Dr. McGuire replied that the FDA made the package insert carry the same side effects as the rest of the beta blocker class. Much of the literature would support that it's probably safer to use in patients with respiratory disease because of its beta selectivity. It also has less impact on metabolic effects (glucose, lipids) and it is much better tolerated.

MARK OLEY REVIEWED THE NEW BETA-ADRENERGIC BLOCKING AGENT BYSTOLIC™

Nebivolol (Bystolic™) is a beta blocker indicated for the treatment of hypertension, either alone or in combination with other antihypertensive medications. It is once a day and has been shown to be effective in the African American population. Common side effects, contraindications, and indications are similar to other beta blockers and can be considered class effects.

New Drugs in PDL Phase 1- Ace Inhibitors

MARK OLEY REVIEWED ACE INHIBITORS

A new dosage form Altace Tablet, and a new first time generic Ramipril for Altace Capsule, are now available on the market.

New Drugs in PDL Phase 1- Ace Inhibitors/Calcium Channel Blockers

MARK OLEY REVIEWED ACE INHIBITOR/ARB CALCIUM CHANNEL BLOCKER

AZOR™ is a new combination product of an Angiotensin Receptor Antagonist and a Calcium Channel Blocker ((Norvasc) amlodipine/(Benicar) olmesartan medoxomil)). Azor may be substituted as similarly dosed for its individually titrated components for patients on both amlodipine and (Benicar) olmesartan medoxomil. Contraindications, precautions and drug interactions, and common side effects are the same as the individual components.

Mark Oley motioned for Azor™, Bystolic™, Altace Tablet and the new first time generic Ramipril for Altace Capsule to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Azor™, Bystolic™, Altace Tablet and the new first time generic Ramipril for Altace Capsule as PDL eligible.

New Drugs in PDL Phase I Review: Combination Lipotropics Non-Statins: Niacin Derivatives-Simcor®

Marija Tesic-Schnell, PhD, Clinical Science Manager, Global Pharmaceutical Research & Development Division, Abbott Laboratories, discussed Simcor® (HMG CoA Reductase Inhibitors and Combinations Statins)

Dr. Axelrod asked if Simcor® should be taken in the evening or in the morning because of the effects. Dr. Tesic-Schnell replied that it is recommended to take Simcor® in the evenings so the flushing can take place while you are sleeping.

Dr. Axelrod confirmed that Simcor is a QHS drug. Dr. Tesic-Schnell said yes.

Dr. Axelrod asked what the aspirin dose is that is recommended to reduce flushing when taking Simcor®.

Dr. Tesic-Schnell stated that aspirin 325 mg is more effective at decreasing flushing with Niapan® as well as Simcor®. She added that there are large individual differences between patients.

TIM JENNINGS REVIEWED THE NEW HMG COA INHIBITORS/ NIACIN EXTENDED-RELEASE COMBINATION DRUG SIMCOR®

Simcor® is a combination of Niacin extended-release/Simvastatin available as an oral tablet in 500/20, 750/20, and 1,000 mg/20 mg. It is a fixed dose 20 mg Simvastatin with increasing strengths of Niacin. Both products are available generically. Both products are very effective at improving cholesterol levels. Niacin has some of the largest HDL raising capabilities alone; however, Niacin does not have the LDL lowering ability as seen with Simvastatin. The two drugs together are very effective at lowering total cholesterol, LDL, and raising HDL. There is nothing unique with this product and no unique side effects or problems.

Dr. Axelrod asked Tim Jennings to review the highlights of the current data on Vytorin (the ENHANCE Study) with the Committee. Tim Jennings said that the FDA is not going to request an official change in the labeling of Vytorin based on this study. The Committee discussed the information reviewed and the possible significance.

Tim Jennings motioned that Simcor® be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Simcor® as PDL eligible.

New Drug in PDL Phase 1- Second-Generation Antihistamine Class

MARK OLEY REVIEWED NEW DRUGS IN THE ANTIHISTAMINES – SECOND GENERATION CLASS

There are two new generic OTCs: Cetirizine/ pseudoephedrine (Zyrtec-D®) and Cetirizine (Zyrtec®). Zyrtec-D® is a combination of a low-sedating antihistamine and a nasal decongestant and Zyrtec® is a low-sedating antihistamine. The nonprescription approval of Zyrtec® includes 5 mg and 10 mg oral and chewable tablets and 1 mg/mL oral syrup.

Allegra has a new dosage form, an Orally Degenerating Tablet (ODT).

The FDA has approved additional labeling for the over-the-counter non-sedating antihistamine (Loratadine (Claritin®)) to clearly indicate that it relieves the symptoms of both perennial (in-door) and seasonal (outdoor) allergies.

Mark Oley motioned for New Generic and OTC-Cetirizine/ pseudoephedrine (Zyrtec-D®) and Cetirizine (Zyrtec®) to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider the New Generic and OTC-Cetirizine/ pseudoephedrine (Zyrtec-D®) and Cetirizine (Zyrtec®) as PDL eligible.

New Drug in PDL Phase I- Proton Pump Inhibitors Class

TIM JENNINGS REVIEWED PROTON PUMP INHIBITORS

Protonix has generic Pantoprazole that has been released.

Tim Jennings motioned for first-time generic Pantoprazole to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider the first-time generic Pantoprazole as PDL eligible.

New Drugs in PDL Phase I Review- Electrolyte Depleters

MARK OLEY REVIEWED ELECTROLYTE DEPLETERS

New Electrolyte Depleters Renvela™ (sevelamer carbonate) is available as an 800mg oral tablet.

Sevelamer carbonate (Renvela) is a phosphate binder indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis. The initial dose is one to two 800 mg tablets three times per day with meals. The safety and efficacy of sevelamer carbonate (Renvela) is the same as other drugs in this class. One head-to-head study reported within the class showed no real difference between products. Contraindications, precautions, and drug interactions are very similar.

Mark Oley motioned for Renvela™ to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Renvela™ as PDL eligible.

Phase II PDL Annual Review- Oral Hypoglycemics

Vanessa L. Land, PharmD, Senior Regional Medical Scientist/Clinical Development & Medical Affairs, Metabolic Division, GlaxoSmithKline Pharmaceuticals, discussed Avandamet®, Avandia® and Avandaryl™ (Biguanide Combination Products)

Tim Jennings asked how the market share for Avandia changed with the question of increased cardiovascular risk that may be associated with Avandia.

Dr. Land replied that the market share did fall nationally when this information was originally released. She said that there was a dramatic reduction of the entire TZD class. The FDA has updated the label.

The market share is now flat, but it is beginning to increase again.

Tim Jennings noted that he has seen a dramatic reduction in the use of Avandia over the past year (around the same time that Januvia came out).

Kelly Hollenack, PharmD, CGP, FASCP, Senior Clinical & Outcomes Manager, Takeda Pharmaceuticals America, Inc., discussed Actos®, Actosplusmet®, and Duetact® (Thiazolidinediones).

No questions or comments from the Committee.

TIM JENNINGS REVIEWED ORAL HYPOGLYCEMICS: BIGUANIDES AND COMBINATIONS

Metformin, now available generically and has been for many years, is a very good product. Most agents now have a combination product with Metformin. It is the gold standard of hypoglycemic agents and diabetes treatment for patients that do not have renal insufficiency. Definitely the first-line drug out there.

TIM JENNINGS REVIEWED ORAL HYPOGLYCEMICS: SECOND GENERATION SULFONYLUREAS

The Second Generation Sulfonylureas are used for second-line therapy. While they are effective in reducing HbA1c, they may produce more episodes of hypoglycemia than other second-line treatments. *Post meeting clarification: Glimpiride (Amaryl) and Glipizide (Glucotrol, Glucotrol XL) are in Pregnancy Category C and glyburide (Diabeta, Glynase, Micronase) products are in Pregnancy Category B.*

TIM JENNINGS REVIEWED ORAL HYPOGLYCEMICS: ALPHA-GLUCOSIDASE INHIBITORS

Alpha-Glucosidase Inhibitors are commonly used as add-on therapy once other treatments are deemed insufficient or are not tolerated.

TIM JENNINGS REVIEWED ORAL HYPOGLYCEMICS: MEGLITINIDES

Post meeting clarification: The 2007 American Diabetes Association (ADA) Position Statement does not include Meglitinides in their treatment algorithm. Both Nateglinide (Starlix) and repaglinide (Prandin) are in Pregnancy Category C. Dosage adjustments are recommended for severe renal impairment and moderate to severe hepatic failure.

TIM JENNINGS REVIEWED ORAL HYPOGLYCEMICS: THIAZOLIDINEDIONES

A boxed warning was added to the product labeling for Thiazolidinediones and its Combinations (Avandia®, Actos®, Avandaryl®, Avandamet®, Duetact®, Actoplus Met®) to emphasize that these drugs may worsen congestive heart failure in certain patients. Rosiglitazone (Avandia®) has information in its package insert about the increased risk of heart attack seen in the meta-analysis.

Tim Jennings motioned that Oral Hypoglycemics (Biguanides, Biguanide Combination, Second Generation Sulfonylureas, Alpha-Glucosidase Inhibitors, Meglitinides, and Thiazolidinediones) continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider Oral Hypoglycemics (Biguanides, Biguanide Combination, Second Generation Sulfonylureas, Alpha-Glucosidase Inhibitors, Meglitinides, and Thiazolidinediones) as PDL eligible.

Phase II PDL Annual Review- Antivirals: Ophthalmic Class

Renee Bovellet, MD, Practicing Ophthalmologist in Virginia, DC, and Maryland, discussed Xalatan. Dr. Bovellet noted that she is a speaker for Pfizer.

Gill Abernathy asked if there was any long-term negative outcomes from iris periocular pigmentation. Dr. Bovellet said that no there is not.
Dr. Axelrod asked if iris periocular pigmentation had any impact on light rebound.
Dr. Bovellet said that it does not.

Teresa L. Brevetti, MD, Fellowship-Trained Glaucoma Specialist, Director, Research and Medical Specialist, Pfizer Ophthalmics, discussed Xalatan

No questions or comments from the Committee.

Richard Fiscella, RPh, MPH, Clinical Professor, Department of Pharmacy Practice, Adjunct Assistant Professor, Department of Ophthalmology, University of Illinois at Chicago, discussed Combigan®

No questions or comments from the Committee.

MARK OLEY REVIEWED GLAUCOMA ALPHA-2 ADRENERGIC

The new combination drug Combigan™ made by Allergan is a combination of an alpha-adrenergic receptor agonist with a beta-adrenergic receptor blocker indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive therapy or replacement therapy due to inadequately controlled IOP. There is a possible increased compliance with this combination product because there is no waiting time in-between drops.

MARK OLEY REVIEWED GLAUCOMA CARBONIC ANHYDRASE INHIBITORS & GLAUCOMA PROSTAGLANDIN ANALOGS

There have been no significant changes in this class over the past year.

MARK OLEY REVIEWED OPHTHALMIC ANTI-INFLAMMATORY (NSAID)

There have been no significant changes in this class over the past year.

MARK OLEY REVIEWED OPHTHALMIC QUINOLONES

There is now a 1.5% solution of Levofloxacin available (Iquix®). It's an Ophthalmic Solution.

MARK OLEY REVIEWED OPHTHALMIC ANTIHISTAMINES & OPHTHALMIC MAST CELL STABILIZERS

There have been no significant changes in this class over the past year.

Mark Oley motioned that all Ophthalmics continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Ophthalmics as PDL eligible.

Phase II PDL Annual Review- Antivirals: Herpes and Influenza Class

Heather F. Crouch, PharmD, Senior Regional Medical Scientist II, Vaccines/Anti-Infectives Division, GlaxoSmithKline Pharmaceuticals, discussed Relenza (zanamivir)

Gill Abernathy asked if we have seen any abnormal behavior in the United States similar to what has been seen in Japan.

Dr. Crouch replied that, while they did have to amend the package insert, we have not seen the type of incidence that was noted in Japan. No causal relationship was found.

Phase II PDL Annual Review- 2nd & 3rd Generation Cephalosporins

TIM JENNINGS REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: 2ND & 3RD GENERATION CEPHALOSPORINS

A new generic of Omnicef® was released-Cefdinir. It is available generically for both the tablet and suspension. Liquids are available currently. Other than that, there really are no changes in the 2nd and 3rd generation.

Phase II PDL Annual Review- Macrolides Adult and Pediatric

TIM JENNINGS REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: MACROLIDES ADULT AND PEDIATRIC AND KETOLIDES

Tim Jennings said that both have generic formulations.

Phase II PDL Annual Review-Oral Antifungals for Onychomycosis

TIM JENNINGS REVIEWED ORAL ANTIFUNGALS FOR ONYCHOMYCOSIS-

The FDA approved a new dosage form of Lamisil® Oral Granules (Terbinafine) made by Novartis. It is an Allylamine antifungal agent now approved in an oral granules formulation which can be sprinkled on food for treatment of tinea capitis in children ages four years and older.

TIM JENNINGS REVIEWED ANTIVIRALS: HERPES AND INFLUENZA

There have been no significant changes in the Herpes class over the past year.

In terms of Influenza, on September 19, 2007, the FDA approved a new indication for FluMist® made by MedImmune. The nasal influenza vaccine, which contains a weakened form of the live virus, and was previously limited for use in healthy children five years of age and older and to adults up to 49 years of age, is now approved for use in children between two and five years of age.

Tim Jennings motioned that all Cephalosporins, Macrolides, and Antivirals classes be PDL eligible. The motion was seconded. The Committee voted unanimously to consider all Cephalosporins, Macrolides, and Antivirals classes as PDL eligible.

Christine Arsever, MD, Senior Medical Director, Merck & Co., discussed Singulair

No questions or comments from the Committee.

MARK OLEY REVIEWED LEUKOTRIENE MODIFIERS AND LEUKOTRIENE FORMATION INHIBITORS

Mark Oley mentioned the suicide tendencies association with Singulair. The FDA anticipates that it may take up to 9 months to complete the on-going evaluations regarding the suicide tendencies. As soon as this review is complete, the FDA will communicate the conclusions and recommendations to the public.

Mark Oley motioned that Zylflo is now discontinued. Zylflo XR is on the market. Mark Oley said that he doesn't think it is being used in Virginia.

Mark Oley motioned that leukotriene modifiers and leukotriene formation inhibitors be PDL eligible. The motion was seconded. The Committee voted unanimously to consider leukotriene modifiers and leukotriene formation inhibitors as PDL eligible.

Phase II PDL Annual Review-Analgesics

Laurie J. Cooksey, Clinical Pharmacist, Assistant Clinical Professor, VCU Medical Center, discussed Celebrex (celecoxib) and is a speaker for Purdue, Pharma, and Pfizer.

No questions or comments from the Committee.

Maureen E. Corson, PharmD, Director, Regional Medical Research Specialist, Pfizer, discussed Celebrex (celecoxib)

No questions or comments from the Committee.

MARK OLEY REVIEWED ANALGESICS: NSAID WITH COX-2 INHIBITORS NSAIDS

The new drug Diclofenac epolamine (Flector®) is the first topical NSAID (non-steroidal anti-inflammatory drug) transdermal patch to be available in the United States. It is indicated for topical treatment of acute pain due to minor strains, sprains, and contusions. The package labeling includes the class black box warning for all NSAIDs regarding the possible risk of serious cardiovascular thrombotic events including potentially fatal myocardial infarction and stroke and serious gastrointestinal adverse

events such as bleeding, ulceration, and perforation. The Diclofenac Patch has many of the same drug interactions as those seen with oral NSAID therapy.

The new drug Voltaren Gel (diclofenac sodium 1% topical gel) has been approved as the first topical prescription treatment for osteoarthritis pain. Voltaren Gel, a nonsteroidal anti-inflammatory drug, is recommended for use in treating pain associated with osteoarthritis in joints that can be managed with topical treatment, such as the knees and hands. The side effects are similar to that of nonsteroids. It's a little less because the absorption is 94% less than that of oral diclofenac.

MARK OLEY REVIEWED ANALGESICS LONG ACTING NARCOTICS-

The opioid agonist and Schedule II controlled substance, Oxycodone Controlled Release (OxyContin®), is now available in three new dosage strengths: 15 mg, 30 mg, and, 60 mg tablets.

Opana ER® (Oxymorphone Extended Release) Extended-release opioid analgesic is now approved in strengths of 7.5, 15, and 30 mg tablets.

There have been some issues accruing both brand and generic Fentanyl Patches over the past few months.

Mark Oley motioned that NSAID with COX-2 inhibitors and Long Acting Narcotics classes continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider NSAID with COX-2 inhibitors and Long Acting Narcotics classes as PDL eligible.

Phase II PDL Annual Review-Osteoporosis: Bisphosphonates

TIM JENNINGS REVIEWED OSTEOPOROSIS: BISPHTHOSPHONATES

Alendronate (generic Fosamax®) bisphosphonate and calcium regulator are now approved in generic versions. Teva Pharmaceuticals received approval to manufacture three once daily dosing strengths (5, 10, and 40 mg) and two weekly dosing strengths (35 and 70 mg). Barr Laboratories, Inc., received approval to manufacture a once weekly 70 mg dosage strength.

For all Bisphosphonates, the FDA is highlighting the possibility of severe and sometimes incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates.

Tim Jennings motioned that Bisphosphonates continue to be PDL eligible. The motion was seconded. The committee voted unanimously that Bisphosphonates continue as PDL eligible.

Phase II PDL Annual Review-Osteoporosis: Serotonin Receptor Agonists (TRIPTANS)

MARK OLEY REVIEWED SEROTONIN RECEPTOR AGONISTS (TRIPTANS)

There have been no significant changes in this class, but Mark Oley mentioned that an upcoming change is the generic Imitrex is scheduled to be released in the late winter of 2008.

Mark Oley motioned that Serotonin Receptor Agonists (Tryptans) continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider the Serotonin Receptor Agonists (Tryptans) as PDL eligible.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL

Ms. Usha Koduru from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 33 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 33 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b)(3)(D) requires such pricing information to be kept confidential. On this point, federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information she cautioned only this confidential information should be discussed.

Mark Oley made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

This motion was seconded and unanimously approved by the Committee.

The meeting adjourned to an executive session.

The Committee returned to the room.

Mark Oley confirmed that to the best of each of the Committee member's knowledge the only information discussed at the confidential meeting was information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

Phase II PDL Annual Review ~ PDL status changes and new class additions effective July 1, 2008 unless otherwise noted

Mark Oley made a motion to maintain the current PDL with only the following change in the CNS Stimulant/Antihyperkinesia class: add Vyvanse® as preferred. The motion was seconded and the Committee voted unanimously to make the stated change. Dr. Axelrod noted that Dexedrine Spansules have been discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Bisphosphonates class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Bisphosphonates class with no change, but with the agreement to re-evaluate the class in six (6) months.

Mark Oley made a motion to maintain the current PDL with the following change in the Quinolones class: add Cipro susp recon ® as preferred and move Ofloxacin tablet and Ciprofloxacin HCL susp to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made a motion to maintain the current PDL Prostaglandin Agonists-Ophthalmic class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Prostaglandin Agonists-Ophthalmic class with no change. It was noted that Rescula has been discontinued from the market and will be removed from the class.

Dr. Axelrod asked that a draft policy be developed and reviewed at the next meeting that addresses removing drugs from the PDL once they are no longer available and have been removed from the market.

Mark Oley made a motion to maintain the current PDL with the following change in the Ophthalmic Antihistamines class: move Ketotifen Fumarate Drops to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated change.

Mark Oley made a motion to maintain the current PDL Third Generation Cephalosporins class with the following changes: add cefdinir capsule and cefdinir susp recon as preferred and move Omnicef capsule and Omnicef susp recon to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated changes. (*Post Meeting Clarification: A stray mark on the paper caused cefpodoxime proxetil to be read as preferred but it was confirmed with Dr. Axelrod that the intention of the Committee was to maintain cefpodoxime proxetil as non-preferred.*)

Mark Oley made a motion to maintain the current PDL with only the following change in the Second generation Cephalosporins class: move Ceftin susp recon to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated change. It was noted that Ceclor, Ceclor, Lorabid, and Lorabid susp have been discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Onychomycosis Antifungals class with no change. The motion was seconded and the Committee voted unanimously to maintain the current class with no change.

Mark Oley made a motion to maintain the current PDL Beta Blockers-glaucoma class with only the following change: add Combigan as preferred. The motion was seconded and the Committee voted unanimously to make the stated change.

Mark Oley made a motion to maintain the current PDL Proton Pump Inhibitors class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Proton Pump Inhibitors class with no change.

Mark Oley made a motion to maintain the current PDL Low Sedating Antihistamines class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Low Sedating Antihistamines class with no change.

Mark Oley made a motion to maintain the current PDL with only the following changes in the Urinary Tract Antispasmodics class: add Sanctura XR as preferred and move oxybutynin chloride ER to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made a motion to maintain the current PDL Beta Blockers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Beta Blockers class with no change.

Mark Oley made a motion to maintain the current PDL Ace Inhibitors class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Ace Inhibitors class without change.

Mark Oley made a motion to maintain the current PDL Electrolyte Depleters class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Electrolyte Depleters class with no change.

Mark Oley made a motion to maintain the current PDL ARB/CCB Combinations class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL ARB/CCB Combinations class with no change.

Mark Oley made a motion to maintain the current PDL NSAIDS class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL NSAIDS class with no change.

Mark Oley made a motion to maintain the current PDL Leukotriene Modifiers class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Leukotriene Modifiers class with no change. It was noted that Zyflo has been discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Macrolides –Adult class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Macrolides – Adult class with no change. It was noted that Dynabac has been discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Macrolides-Pediatrics class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Macrolides-Pediatrics class with no change.

Mark Oley made a motion to maintain the current PDL Thiazolidinediones-Oral Antidiabetic class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Thiazolidinediones-Oral Antidiabetic class with no change.

Mark Oley made a motion to maintain the current PDL Serotonin Receptor Agonists class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Serotonin Receptor Agonists class with no change.

Mark Oley made a motion to maintain the current PDL Antivirals class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Antivirals class with no change.

Mark Oley made a motion to maintain the current PDL Second Generation Sulfonylureas class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Second Generation Sulfonylureas class with no change.

Mark Oley made a motion to maintain the current PDL Hypoglycemics, Biguanide Type class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Hypoglycemics, Biguanide Type class with no change.

Mark Oley made a motion to maintain the current PDL Ophthalmic Quinolones class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Ophthalmic Quinolones class with no change.

Mark Oley made a motion to maintain the current PDL Receptor Selective NSAIDS class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Receptor Selective NSAIDS class with no change.

Mark Oley made a motion to maintain the current PDL Thiazolidinedione-Metformin Combinations class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Thiazolidinedione-Metformin Combinations class with no change.

Mark Oley made a motion to maintain the current PDL Influenza class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Influenza class with no change. It was noted that Symmetrel and Symmetrel Syrup have been discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Carbonic Anhydrase Inhibitors-Glaucoma class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Carbonic Anhydrase Inhibitors-Glaucoma class with no change.

Mark Oley made a motion to maintain the current PDL Meglitinides- Oral Antidiabetic class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Meglitinides- Oral Antidiabetic class with no change.

Mark Oley made a motion to maintain the current PDL Alpha 2 Adrenergic Agents- Glaucoma class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Alpha 2 Adrenergic Agents- Glaucoma class with no change. It was noted that Alphagan was discontinued from the market and will be removed from the class.

Mark Oley made a motion to maintain the current PDL Ophthalmic NSAIDS class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Ophthalmic NSAIDS class with no change.

Mark Oley made a motion to maintain the current PDL Alpha-Glucosidase Inhibitors-Oral Antidiabetic class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Alpha-Glucosidase Inhibitors-Oral Antidiabetic class with no change.

Mark Oley made a motion to maintain the current PDL Ophthalmic Mast Cell Stabilizers class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Ophthalmic Mast Cell Stabilizers class with no change.

Mark Oley made a motion to maintain the current PDL Thiazolidinedione-Sulfonylurea Combinations class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Thiazolidinedione-Sulfonylurea Combinations class with no change.

Mark Oley made a motion to maintain the current PDL Hypoglycemics, Biguanide and combinations class with no change. The motion was seconded and the Committee voted unanimously to maintain the current PDL Hypoglycemics, Biguanide and combinations class with no change.

The Committee reviewed the current PDL criteria for the Long Acting Narcotics – Step Therapy. The motion was made to maintain the current PDL Long Acting Narcotics – Step Therapy criteria as written. The motion was seconded and the Committee voted unanimously to accept the PDL criteria as written with no change.

Mark Oley made a motion to maintain the current PDL with the following change in the Long Acting Narcotics class: move Oramorph to non-preferred. The motion was seconded and the Committee voted unanimously to make the stated change.

The Committee reviewed all Phase II PDL criteria with a one-year authorization. The motion was made to maintain the current PDL Phase II criteria as amended. *(Post Meeting Clarification: The change came under NSAIDs (Non-Steroidal Anti-inflammatory Drugs). The clinical criteria for Flector® & Voltaren gel® include:*

- *Approval is based on patient failing the ORAL generic of the desired product AND at least 1 other preferred NSAIDs (to equal a total of at least 2 preferred).*
- *For example, a patient who failed ibuprofen and naproxen will still need to try oral generic diclofenac for approval of Flector.)*

The motion was seconded and the Committee voted unanimously to maintain the current Phase II criteria as amended.

The committee reviewed all Phase II criteria with up to 6 months authorization. The motion was made to maintain the current PDL Phase II criteria as amended. *(Post Meeting Clarification: The change came under Antifungals (Oral) for Onychomycosis. A PA for Lamisil® granules may be granted if:*

- *Recipient is over 4 years of age*
- *Diagnosis is tinea capitis*

Lamisil® oral granules are FDA approved for the treatment of tinea capitis (also called ringworm of the scalp) in patients 4 years of age and older. (Lamisil® oral tablets (250mg) are FDA approved for the treatment of tinea unguium- onychomycosis but not tinea capitis ringworm.)

The motion was seconded and the Committee voted unanimously to maintain the current Phase II criteria as amended.

The committee reviewed all Phase II criteria with no refill authorization. The motion was made to maintain the current PDL Phase II criteria as written. The motion was seconded and the Committee voted unanimously to maintain the current Phase II criteria.

The committee reviewed Phase I criteria with a one-year authorization. The motion was made to maintain the current PDL Phase I criteria as written. The motion was seconded and the Committee voted unanimously to maintain the current Phase I criteria.

The committee reviewed Phase I criteria for the PPI class with a recommendation to add Protonix or its generic pantoprazole to the verbage. The motion was made to maintain the current PDL Phase I criteria as amended. The motion was seconded and the Committee voted unanimously to maintain the current Phase I criteria as amended.

Mark Oley motioned to maintain the PA criteria for the current PDL Lipotropics-Non-statins: Niacin derivatives class with the following change: add Simcor as preferred with the requirement that an electronic step edit be met. The step edit must have a history of Niaspan or Simvastatin in order to receive Simcor. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made a motion to add Mupirocin as preferred to the Topical Antibiotic class. Dr Axelrod noted that this would be a generic only class. Altabax® and Bactroban® are non-preferred with a package restriction on Altabax® of 5 grams. With the motion seconded, the Committee voted unanimously to make the stated changes.

The Committee discussed in detail the Oral Hypoglycemic class and considered the need for step therapy. Mark Oley made a motion to add Janumet® and Januvia® as preferred with a request to invite

specialists to the next meeting to review a possible step edit for the Oral hypoglycemic class. With the motion seconded, the Committee voted unanimously to make the stated changes. All other drugs in this class will be non-preferred.

Dr. Axelrod reviewed plans for the next meeting in the Fall of 2008. The meeting was adjourned.

ATTACHMENT

Pharmacy and Therapeutics Committee
*Guidance Document Regarding New Generic Drug Policy
for the Preferred Drug List*

Introduction

The Virginia Medicaid Pharmacy and Therapeutics (P&T) Committee, in its meeting on April 17, 2007, requested the development of a Guidance Document to address the management of generic drugs in classes subject to the Preferred Drug List (PDL). Of interest to the Committee was clarifying the conditions in which a new generic drug would be adopted as “preferred” on the PDL; particularly when immediate action is warranted and there are 30 days or more until the next scheduled P&T Committee meeting. The intent was to create a default policy for the management of new generics while maintaining the primary methods of reviewing new generics as a regular part of the P&T Committee meeting agenda. Optimally, the P&T Committee will review pending generics and act upon all new generics during annual drug class reviews. A motion was made and unanimously approved to create a Guidance Document to develop a policy to address this issue.

One recommendation was to utilize price points as a method of determining when generic drugs should be considered for preferred status on the PDL. In addition, the Committee’s discussion included the potential removal of brand name drugs from preferred status when therapeutically equivalent generic drugs are more cost effective. This Guidance Document outlines current policies and proposed guidelines for the future management of new generics in drug classes subject to the PDL.

Objective

The goal of the policy is to achieve more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes.

Guidelines will be developed to allow the Department to take interim actions, in the absence of a P&T Committee discussion, which are in the best financial interest of the Commonwealth. The policy will not address clinical issues where health and safety concerns are present because all drugs involved are therapeutically equivalent. This policy recognizes that the PDL is mature and the most significant changes now relate to the introduction new generics in established PDL-eligible drug classes.

Current New Drug Policies

Since its inception, the P&T Committee has adhered to policies for reviewing new drugs in therapeutic classes subject to the PDL as well as a specific new generic drug policy (See “[Preferred Drug List Generic Policy](#)” and “[Process for Reviewing New Drugs](#)” at the following link: http://www.dmas.virginia.gov/pharm-p&t_committee.htm). Under the current policy, as the Food and Drug Administration (FDA) approves a new drug product in a class previously reviewed and deemed “PDL-eligible” by the P&T Committee, the drug is immediately considered non-preferred and requires prior authorization. Further determination of the drug’s status is typically conducted by the P&T Committee at its next meeting; however, current guidelines allow the Department’s Director to change new generics to preferred, in consultation with the P&T Committee Chair, if he chooses, where drugs are therapeutically equivalent and cost information warrants this change. This process includes a review of supplemental rebate contracts to ensure there are no conflicts as well as appropriate notification to P&T Committee members and public stakeholders.

Item 302 S.2.b (Chapter 847) of the 2007 General Assembly Appropriations Act requires that the P&T Committee schedule meetings at least quarterly to review any drug in a class subject to the PDL that is newly approved by the FDA, provided there is at least thirty (30) days notice of approval prior to the

quarterly meeting. First Health Services Corporation (FHSC) monitors all new drugs (brand and generic) in PDL- eligible classes introduced in the market through weekly updates from First DataBank (FDB) and notifies the Department of changes. A drug will be considered eligible for P&T Committee review if it meets one of the following criteria:

- A “new brand” drug defined by the FDA as having the new drug application (NDA) approved which indicates that the product may be marketed in the United States
- A “new brand of an established generic” and has met the FDA definition above of “new brand”
- A “First Generic” on the monthly FDA update of “Generic Drug Approvals”. First Generics are those drug products that have not previously been approved as generic drug products and are new to the marketplace.

Drugs that meet these criteria are included on the agenda of the next P&T Committee meeting for review, regardless of whether an annual review is conducted for the respective drug class. New, non-branded generic drugs within a drug class previously evaluated by the P&T Committee are deemed the same PDL status (preferred or non-preferred) as the existing generic drugs in the related class and therefore, will be addressed at the next annual review of the class.

FHSC makes recommendations for the PDL status of the drug based on the determination of its potential “cost advantage”. The “cost advantage” is currently determined by the final net cost, which is the cost to the Commonwealth net of all federal (CMS) and supplemental rebates. When comparing the final net cost of the generic to the brand, the lesser cost determines which drug presents the greatest “cost advantage”. At the point the cost difference of the generic is neutral or in the best interest of the Department, a recommendation is made to change the status of the generic to preferred along with the brand. With the P&T Committee’s next annual review of the class, it may also be recommended to change the brand to non-preferred.

The new generic drug policy will be integrated with existing policies to clarify interim actions in the absence of a P&T Committee discussion.

Recommendations for Future Management of New Generic Drugs on PDL

The following changes or clarifications are recommended to the current new drug policies when brand drug A is preferred and a new generic of drug A is released to the market or scheduled for release to the market:

Procedural Change/ Clarification

1. A “new generic watch list” will be established and updated on an ongoing basis with all new generics in PDL-eligible classes as they enter the market or are anticipated (with FDA-approval). This will include both first time generics as well as multi- source generics that affect the marketplace. On a quarterly basis, the “new generic watch list” will be sent via e-mail to the Department, P&T Committee Chair and another P&T Committee member. This document will contain the PDL class name; the generic and brand names; the current PDL status of both the brand and generic; information on Federal Upper Limit (FUL) or Maximum Allowable Cost (MAC) price, if they exist; summary of financial comparison; number of manufacturers; recommendations for PDL action; and other pertinent information. Also sent quarterly will be an updated PDL criteria showing all brands and generics as well as their PDL status. A generic watch list or update will be sent on an ad-hoc basis if pricing changes dictate that more immediate review and action are required by the Department.

2. Within two weeks of the new generic drug's pricing information being posted to First DataBank, Virginia Medicaid's drug database, FHSC will evaluate the financial impact; the final net cost (drug cost minus all rebates) of preferred brand A will be compared to the final net cost of generic A. This pricing evaluation of new generic drugs will include consideration of the current FUL and MAC pricing, if they exist. *The publishing of the generic price on FDB is an indication that the generic is widely available in the market.* This information will be included on generic watch list and sent on a quarterly or ad hoc basis to the Department, P&T Committee Chair, and another P&T Committee member.
3. All supplemental rebate contract addendums proposed by manufacturers must be thoroughly reviewed to ensure there are no provisions in conflict with this policy.
4. The PDL Quicklist and criteria will be updated and posted to the DMAS and FHSC web sites within a week of any decisions made by the Department's Director, who may consult with the P&T Committee Chair or another member of the P&T Committee, outside of a P&T Committee meeting.

Decision-Making Changes/ Clarification

1. FHSC will advise of the product with the best cost advantage to the Department. At the time the generic and brand drugs are equivalent in final net cost, FHSC will recommend to the Department that the generic drug become preferred and the brand drug non-preferred. *This is recommended because the generic typically begins to be reimbursed at the MAC or FUL once the generic price becomes equivalent to the brand; these pricing methodologies commonly create the lowest price.* FHSC will consider the financial impact on supplemental rebate collections before recommending a brand agent be removed from preferred status on the PDL. The final decision is made by the Department's Director who may consult with the P&T Committee Chair or another Committee member.
2. If there is a need for immediate action, the Department's Director may consult with the P&T Committee Chair or another Committee member to determine the status of new generics in PDL eligible classes. Immediate action will be necessary if there are 30 days or greater until the next P&T Committee meeting and there is widespread market availability of the new generic. FHSC's recommendations, based on the guidelines above, will be provided for consideration of the drug status. DMAS staff will develop a "decision brief" summarizing the relevant information. Unless there are exceptional circumstances, the guidelines will be applied automatically (systems change to prior authorization requirements) with the approval by the Department's Director. Any actions taken outside of P&T Committee meetings by the Director will be communicated to members via email messages and during their next scheduled meeting.
3. Any decision to change the status of the preferred brand to non-preferred outside of P&T Committee meetings will also be made by the Department's Director in consultation with the P&T Committee Chair or another Committee member. DMAS staff will develop a "decision brief" summarizing the relevant information. Any actions taken by the Department's Director in consultation with the P&T Committee Chair or another Committee member, outside of P&T Committee meetings, will be communicated to members via email messages and during their next scheduled meeting. In addition, the brand drug manufacturer will be notified of the change.
4. All new generics to be reviewed by the P&T Committee will be included on the agenda of its next meeting. FHSC will present an updated "generic watch list" to review market information and recommendations for new generics. The clinical discussion of the new generic drugs will occur in the public meeting; there should be little discussion as these drugs are therapeutically equivalent to the brand already established on the PDL. During the confidential session of the meeting, all of the financial information for each new generic along with the current PDL status

of the related brand and generic products will be reviewed. The Committee will determine the PDL status of the brand and generic drug products as with current practices.

Review by the P&T Committee

All other components of existing new drug policies will remain and these new actions will be integrated into these policies to clarify interim actions in the absence of a P&T Committee discussion. The revised policy will be reviewed by the P&T Committee during an upcoming meeting and published on the DMAS web site. Information on these policy changes may also be included in the next *Medicaid Memorandum* to medical and pharmacy providers that addresses PDL updates.